

NDA 20-428/S-013

27 APR 2001

Allergan
Attention: Mr. Stephen Buxbaum
Director, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Dear Mr. Buxbaum:

Please refer to your supplemental new drug application dated October 12, 2000, received October 13, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azelex (azelaic acid cream), 20%.

We acknowledge the receipt of your submissions dated March 1, and April 17, 2001.

This supplemental new drug application provides for designation of Berlex Laboratories as a distributor of azelaic acid cream, 20%, under the tradename of Finevin (azelaic acid cream), 20%.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-428/S-013." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Olga I. Cintron, R.Ph., Project Manager, at (301) 827-2020.

Sincerely,

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products
DNDC III, Office of Drug Chemistry
Center for Drug Evaluation and Research